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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,521	09/01/2006	Hiroharu Kawahara	125192.00501	1684

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EXAMINER	
KIM, ALEXANDER D	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/591,521	**Applicant(s)** KAWAHARA, HIROHARU	
	Examiner ALEXANDER D. KIM	**Art Unit** 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *20 and 21*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Rebecca E. Prouty/
Primary Examiner, Art Unit 1652

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's amendment after final rejection, filed on 12/09/2008, is acknowledged and has been entered. The said amendment does not appear to have any changes from the previous claims before Final Office Action.

Previous objection to the specifiation is withdrawn by the virtue of Applicants' amendment in the specification reciting "SC-02MFP" and "SC-01MFP".

Applicants' arguments in the amendment filed on 12/09/2008 have been fully considered. However, applicant's arguments are not found persuasive to overcome the outstanding rejection(s) as set forth in the Final Office action mailed on 10/03/2008 for the reasons of record stated therein. Applicants argue that the instant specification (paragraph 0026-0033) on pages 6-8 specifically describe how SC-02MFP may be produced form RMP18226; and SC-01MFP may be produced form KMS-12BM. The instant specification does not used paragraph numbers in the newly filed specification (filed on 12/3/2008); thus, entire pages 6-8 have been considered.

The specification disclose the cell strain SC-01MFP were established from the RPMI8226 cell strain of human myeloma origin; and the SC-02-MFP were established from FERM BP-10077 (see bottom of page 8). However, it is still not clear how to decipher the method of making SC-01MFP and SC-02-MFP such that they are structurally different from the original cell RPM18226 and FERM BP-10077, respectively. The specification, bottom of page 6 to top of page 7, recites that "the inventors of this invention acquired a mutated strain by isolating and selecting a human cell strain form various kinds of human sources that allows a long term stable protein production"; wherein the selection encompasses selecting by the total weight of intracellular protein of cells (see page 7, lines 11-16) and also selecting for cloning rate and doubling time (see page 7, lines 18-24). It is unclear how said isolating and selecting step would produce a mutant strain.

The specification states later on page 8 that "The variant cells obtained as described were induced to mutate in a medium in which nitrosoguanidine, a carcinogenic substance, had been added" and "selected" the mutant. However, it is unclear what kinds of genetic change(s) [i.e., a mutant] were made by the presence of nitrosoguanidine since some population may undergo mutation (if any, since the concentration is unknown and mutagen induced mutation which is concentration dependent) while some population may not undergo mutation. In view of instant specification, there is no evidence that SC-01MFP and SC-02-MFP are mutants induced by the presence of nitrosoguanidine derived from the original cell RPM18226 and FERM BP-10077, respectively. Also, the selection step of cell having cloning rate of over 90% do not contribute to making a mutant as described earlier. Also, the recitation of "The variant cells" in the beginning of page 8 is unclear if it is referring to the various original human cell strain described on top of page 7; or it is referring to the cells after the selection and cloning as described on bottom of page 7 which already selected for over 90% cloning rate.

The specification on page 8, bottom, indicates that the criteria of continuous protein expression of certain period is the criteria for establishing as human cell strain for protein production. However, a cell will continuously expresses a protein as long as a cell is kept in a viable culture condition and the culturing the cell would not contribute to any structural changes such as forming a mutant. As noted in the previous office action, since the Office does not have the facilities for examining and comparing applicants' claimed cell with the cells of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Thus, Claims 20 and 21 are remain rejected over Pene et al. and Hata et al., respectively..